

"A common mistake that people make when trying to design something completely foolproof is to underestimate the ingenuity of complete fools."

From Douglas Adams in "Mostly Harmless"

Trust....But Verify!

How Do you Know

If The Thermometer

Knows What It Knows?

Revaccination due to Non Viable Vaccine

Monday, 17 December, 2001, 11:29 GMT

Meningitis revaccination begins



The first vaccinations followed three deaths in 1999

Thousands of south Wales school children are being vaccinated for the second time after it emerged that an initial vaccination programme failed to protect them from the disease.

The second round of inoculation has started at Porth County Community School in the Rhondda, after two children at the school contracted the disease after having the vaccination two years ago.



It is thought the vaccine used at schools across Rhondda Cynon Taff in 1999 was stored at too low a

NATION

Poorly refrigerated vaccines force new shots for thousands of kids

THE ASSOCIATED PRESS

Tucson, Arizona | Published: 12.05.2007

Every year, thousands of American children go through the tearful ordeal of getting their vaccinations, only to be forced to do it all over again. The vaccines were duds, ruined by poor refrigeration.

It is more than a source of distress for parent and child. It is a public-health threat, because youngsters given understrength vaccines are unprotected against dangerous diseases. And it accounts for a big part of the \$20 million in waste incurred by the federal Vaccines for Children program.

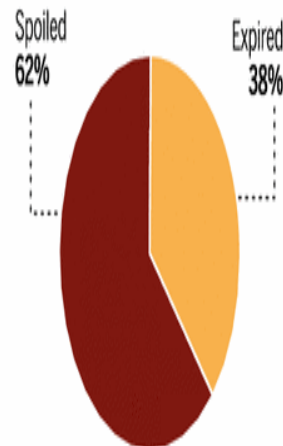
advertisement

"This is a substantial problem that needs to be addressed

Wasted supply

Nearly two-thirds of wasted vaccines are caused by spoilage, according to a report on immunization programs.

Vaccine doses reported wasted



12/05/07 SOURCE: Elsevier

AP

MMWR Report

Flu kills 7 patients in a long term care facility



- 130 residents of a facility
- Medically fragile young people.
- 7 deaths and 10 hospitalizations
- Residents were vaccinated
- Vaccine refrigerator was not monitored
- When investigated average temperature 27 F

Severe Influenza Among Children and Young Adults with Neurodevelopmental Conditions — Ohio, 2011

Children with neurologic and neurodevelopmental conditions are at increased risk for severe outcomes from influenza, including death (1–3). In April 2011, the Ohio Department of Health and CDC investigated an influenza outbreak that began in February 2011 in a residential facility for 130 children and young adults with neurologic and neurodevelopmental

refusing feeding, vomiting, or diarrhea in a resident without laboratory confirmation of influenza. Temperature abnormalities included fever ($\geq 100.4^{\circ}\text{F}$ [$\geq 38.9^{\circ}\text{C}$]) or a 2°F temperature deviation from the mean of three previously recorded quarterly temperatures. A severe case of influenza was a laboratory-confirmed or suspected case that resulted in hospitalization

How Do You Keep Vaccines Safe?

(Which in Pediatrics, is the same thing as saying, How Do You Keep Your Patients SAFE?)

How Do You Keep Vaccines Safe?

The primary risks to vaccines are *thermal excursions* outside of the recommended range – and that risk is asymmetrical! Freezing of refrigerated vaccines assures their destruction; heat merely shortens their life. Both are bad.

How Do You Reduce Thermal Risk?

By having

- Excellent Refrigeration Units
- Excellent Thermometers
- Rapid Notification of Problems
- Excellent Staff

First Let's Discuss Refrigerators

What Makes an Excellent Refrigerator?

Excellent refrigerators are medical-grade with electronic thermostats and visible digital temperature displays, simple adjustable wire shelves, interior circulating fans, ports for temperature probes, door ajar alarms and adequate space!

What does the CDC Recommend in Refrigerators?

They recommend stand-alone units that only refrigerate or freeze and are suitable for vaccine storage.

They currently allow combination domestic units if only the refrigerator section is used and the top shelf is not for vaccine storage.

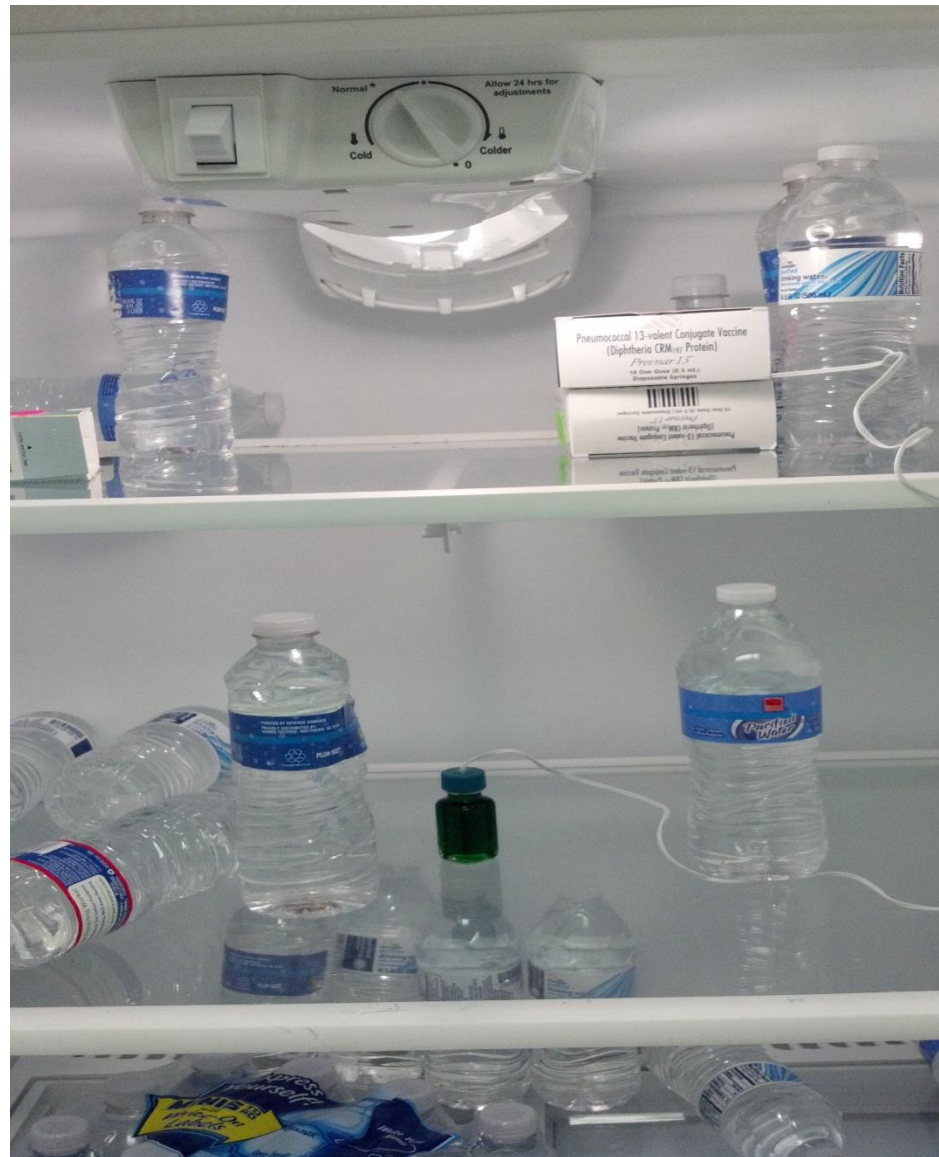
Combo units are much more dangerous and I encourage all practices to replace those ASAP!

What is Wrong With Combo Units?

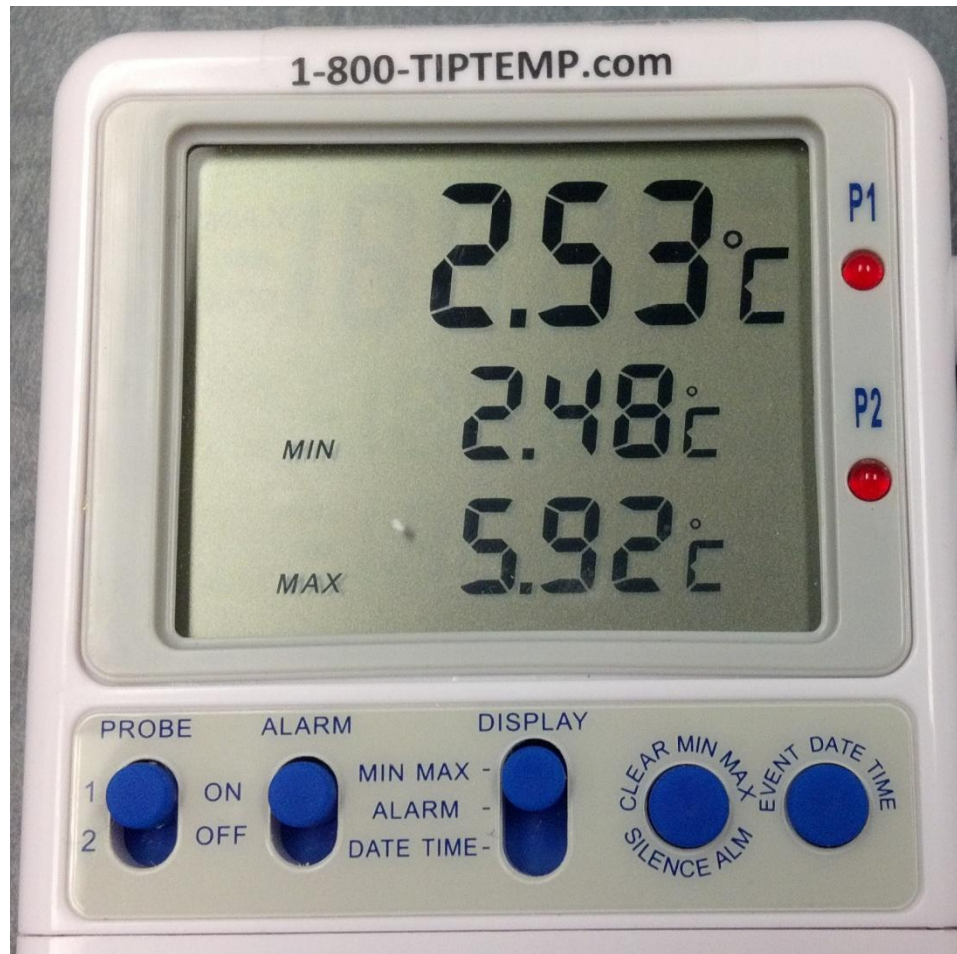
Combo Units are essentially Dorm Refrigerators with an extra door!

All combos and dorm refrigerators have a single thermostat that controls the only evaporator coil which is designed to create air at -18C to -20C. The super chilled air is fed into the refrigerated compartment to chill the contents. If air that is -18C falls onto the top shelf it will freeze any vaccine stored there!

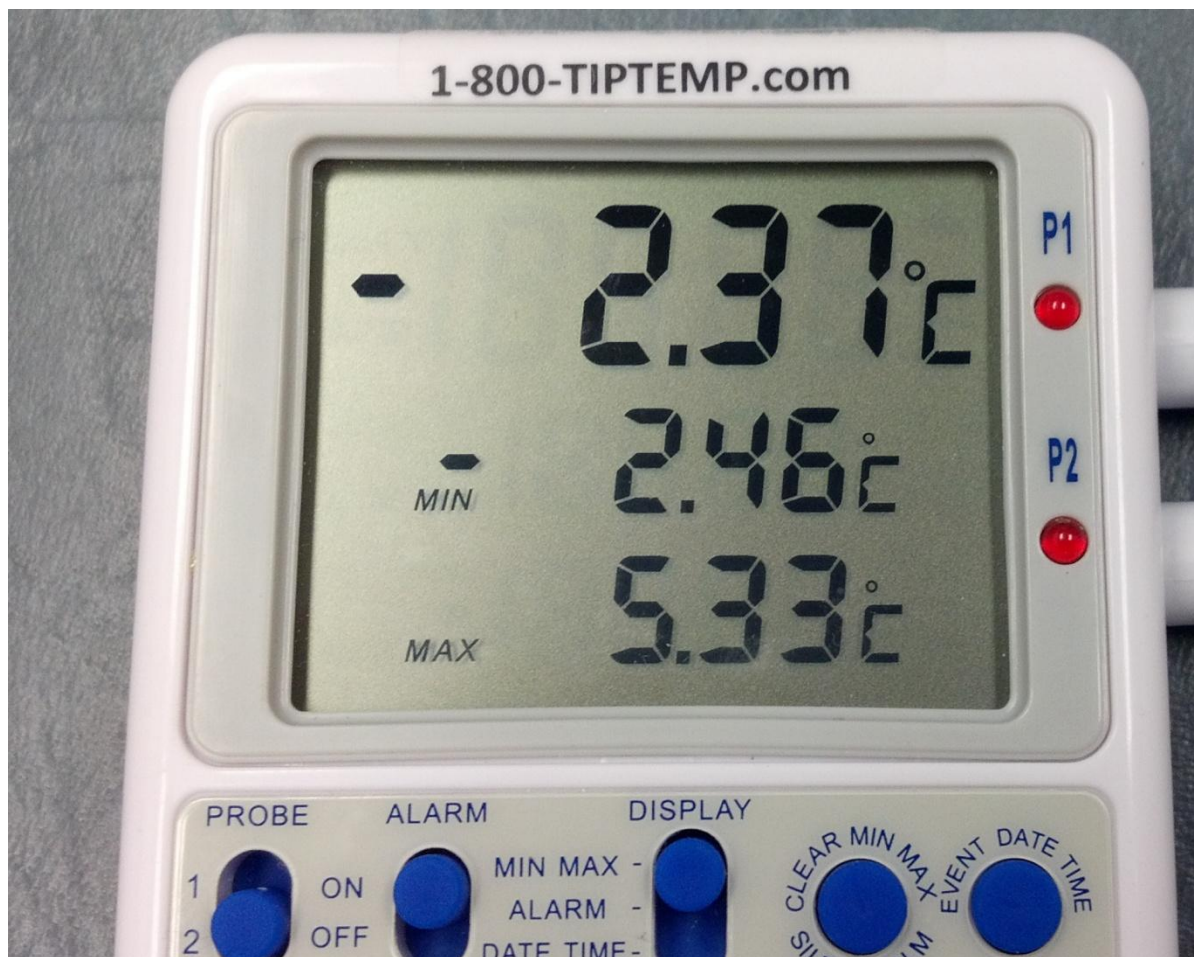
Demonstration Of Top Shelf Freeze



Middle Shelf Glycol Buffered Probe



Top Shelf Glycol Buffered Probe



Why are Refrigerator-Only Units Safer?

They are Safer By Design!

In both Domestic and Medical-Grade units that only refrigerate, the evaporator coils are designed to generate air that is above zero at any setting but “full cold”. If colder, the coils would constantly collect ice! It is much harder to freeze vaccine in a refrigerator-only unit than a combo unit.

Design Matters!

What If The Practice LIKES Their
Combo Refrigerators?

PLEASE!

*Give them my email address and I will
do my best to find them a Real Deal
in medical grade refrigerators!*

DrBarden@CoastalChildrens.com

The most *important link* in the cold chain is

An Excellent Refrigerator!

The way to tell if you have an Excellent Refrigerator is to have an

Excellent Thermometer!

Types of Thermometers

Glass Thermometer - Old fashioned but works; No longer use Mercury; Problematic if they get bumped hard and the liquid separates leaving some at the top

Electronic Thermometer - measures the differential electrical resistance in a probe tip caused by change in external temperature; Rarely changes over time but could – essentially an ohm meter.

Both are usually in a temperature buffer (glycol, glass beads) designed to average sudden change in ambient temperatures

What Makes an Excellent Thermometer?

(My Definition)

The best thermometers are professionally certified with outside mounted digital displays indicating max/min/current temp and interior probe(s) in appropriately sized glycol buffer with data logging storage and preferably phone / internet / SMS capabilities to notify if temperature excursions occur or power fails – all in time to rescue vaccine!

CDC Thermometer Requirements

Next 5 Slides - Page 38&39; S&H Tool Kit CDC November 2012

“CDC recommends using only calibrated thermometers with a Certificate of Traceability and Calibration Testing... Calibrated thermometers are a requirement for providers who receive VFC vaccines or other vaccines purchased with public funds. “

CDC Thermometer Requirements

Certificate of Traceability and Calibration
Testing...

“.....a Certificate of Traceability and Calibration
Testinginforms the user of a
thermometer’s level of accuracy ***compared to
a recognized standard.*** “

CDC Thermometer Requirements

“Thermometer calibration must be tested annually or according to the manufacturer’s recommendation by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body. “

CDC Thermometer Requirements

OR –

“As an alternative by a laboratory or manufacturer that provides documentation that demonstrates that calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability.”

The CDC prefers the first option.

Options When Certificate Expires:

“When the Certificate of Traceability and Calibration Testing expires, CDC recommends one of the following:

- 1) Have the accuracy of your thermometer tested by an accredited laboratory
- 2) Purchase a new thermometer with a Certificate of Traceability and Calibration Testing (also known as a Report of Calibration)”

Options When Certificate Expires (cont'd)

And My Personal Favorite Option:

3) “Contact your immunization program for resources on checking the accuracy of your thermometer”

Option 1 – Recertifying a simple thermometer

- disassembling the probe wires in the refrigerator
- re-assembling NEW probe wires in the refrigerator & setting up the monitor
- shipping off the original and making sure they all come back...
- paying anywhere from \$60 to \$250 each!

Option 1 – Recertifying a sophisticated thermometer

- significant expense for recertification not even counting the hassle factor!
- re-program the phone call / text / email notification features if present
- installing new wires & learning new software for the data logging piece
- teaching staff about the new equipment
- Will have to own spare “set” and mail one off every 6 months to stay certified

Option 2 – Purchase a new certified thermometer

- Significant expense replacing all thermometers, but LESS than recertifying if the minimalist thermometer is purchased
- Will just have to order one every 11 months
- Means manufacturers will start a “race to the bottom” to sell the cheapest device they can!

Let's look at that Option 3....

3) *“Contact your immunization program for resources on checking the accuracy of your thermometer”*

????????

Recent Meeting May 13 at CDC

We (AAP) were told that the CDC has offered some flexibility to grantees allowing end-user ice melting point test validation in addition to commercial re-certification if the state is able to oversee and manage the individual training.

Recent Meeting May 13 at CDC

The AAP in a follow up letter indicated “our biggest ask” was to allow ice melting point test to validate thermometers at the practice level, and then replace or professionally recalibrate if they fail.

The CDC Agreed! The IMP may be acceptable in certain situations when the immunization program agrees and can appropriately oversee it. The individual programs can decide.

Recent Meeting May 13 at CDC

The NIST is strongly in favor of end users doing their own Ice Melting Point Test.

The NC Immunization Program is exploring this as an option – they just need to figure out how to do this with a minimal budget.

The AAP is also exploring how to train its members in doing an IMP.

I think this is a GREAT opportunity to improve the safety of vaccine storage!

CAN an End User do a Traceable
Validation of a thermometer whose
certification has expired?

I say YES with a little bit
of effort and training!

What Does It All Mean?

Verification....

Certification...

Validation....

Traceability....

NIST Definition of Traceability

To establish and maintain traceability, the readings of a thermometer can be compared to a fixed-point temperature (e.g., ice-melting point) or a reference thermometer at a fixed temperature – this testing process is often called verification, performance validation or calibration.

http://www.nist.gov/pml/mercury_traceability.cfm

Don't you need expensive
“Traceable to NIST” equipment to
Re-certify a thermometer or data
logger?

Not according to NIST – we just
need a fixed-point temperature
which is provided by the Ice
Melting Point Test!

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Ice Melting Point Test

Exists because of the definition of 0°C :

“ 0°C is that temperature where water exists in equilibrium in two physical states: Liquid and Ice”

How accurately can you produce a
 0°C temperature?

“If you have access to distilled water and an ice crusher, you can actually achieve an uncertainty of 0.002°C ” ~ NIST web site

Why Learn To Do the IMP?

I hope that we will partner with NIST to design a simple program where VFC Instructors and practice staff can become recognized as competent in this very simple procedure.

Then an IMP can be performed on monitoring equipment and documented by practices as an alternative to professional re-certification!

Why Learn To Do the IMP? (cont'd)

Being able to verify your own electronic thermometers means you can invest in more sophisticated data logging, phone-enabled, internet aware monitoring devices that can call for help BEFORE the vaccine is damaged!

(My practice has a sophisticated \$1300 centralized monitoring system that I am unable to ship off to be re-certified; I would have to pull the wires out of the ceiling & walls! Instead, my “official” thermometers are glass. It is as if we are being asked to listen to an 8-Track player instead of my 32 gig iTouch...)

How easy is it to do an IMP?

Unbelievably Easy!

You just need a container of water and ice mixed in a slurry of more ice than water- and drinking water is fine!

In fact, you can go to any restaurant in town and most will bring you an IMP without even asking if you want one!

Is An IMP Accurate Enough?

A well done IMP can be accurate to $\pm 0.002^{\circ}\text{C}$, which is a factor of 250 times more accurate than the $\pm 0.5^{\circ}\text{C}$ required for vaccine storage!

So even an “adequate” IMP test is able to produce an ice bath reference temperature within a few hundredths of a degree of 0°C !

Is An IMP Accurate Enough?

More importantly, NIST says doing a test of monitoring equipment “As is -- Where is” is The Best and recommends an IMP be done on all newly certified or re-certified equipment before placing in service! Although not a CDC recommendation, this demonstrates that NIST has more faith in a well done IMP on site than a professional certified test done elsewhere and shipped to you bouncing all the way....

How Does An IMP “Verify” a Thermometer?

If you measure a “known” temperature – 0°C – with the thermometer, and it reads $\pm 0.5^{\circ}\text{C}$ of 0°C , you have proven that the thermometer knows where zero is!

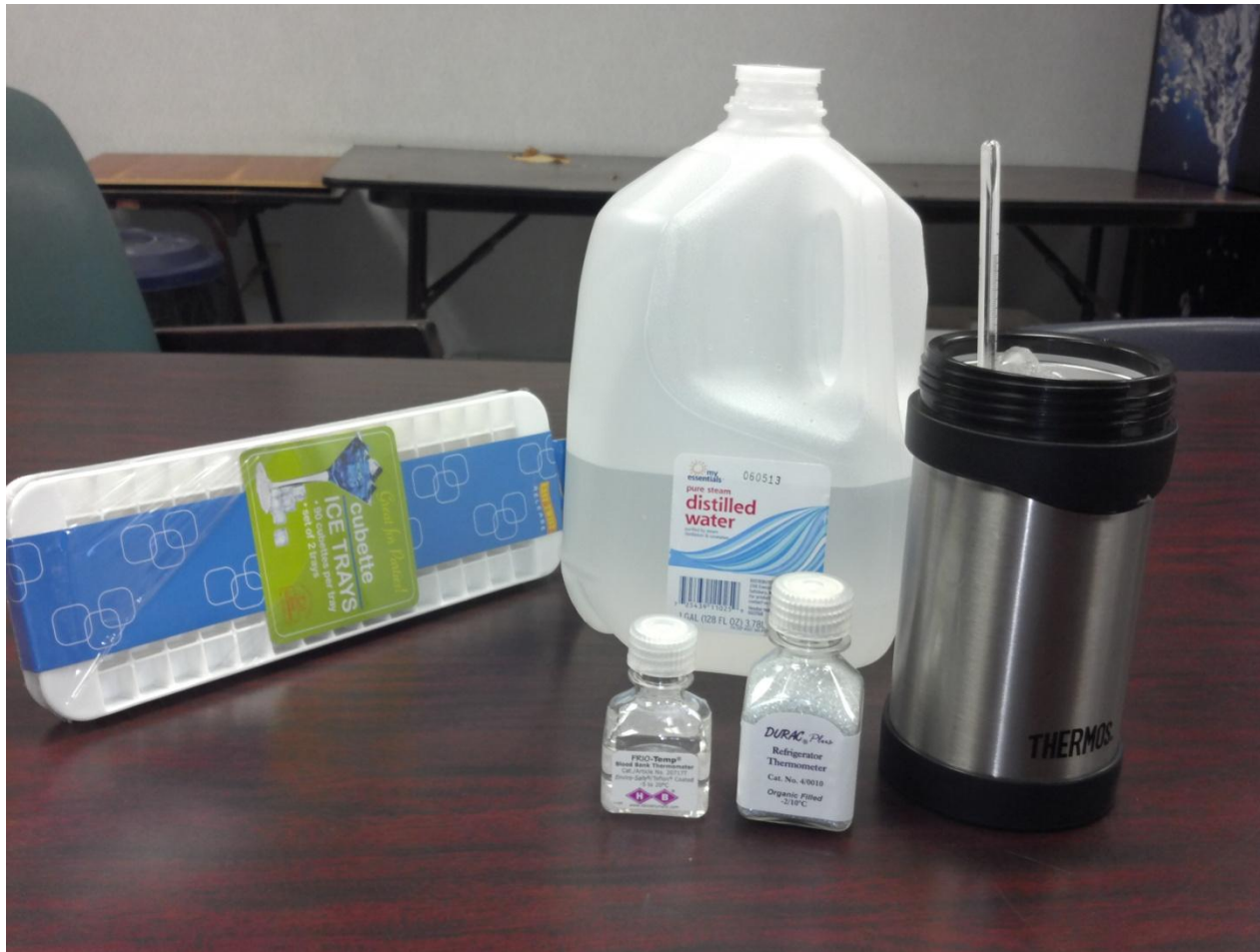
Previously certified thermometers are predictable if the measured temperature matches a known temperature; In this case you are proving the thermometer has not varied or “lost” its calibration!

Why not just compare to another thermometer?

It is much more accurate to test a thermometer by it measuring a known temperature than having two thermometers measuring an unknown temperature and comparing values.

Measurement errors are additive; comparing an uncertified $\pm 0.5^{\circ}\text{C}$ thermometer with a certified $\pm 0.5^{\circ}\text{C}$ thermometer will validate the uncertified thermometer as $\pm 1.0^{\circ}\text{C}$!

IMP Equipment



Performing the IMP

Use a “soup” thermos – large mouth, easy access or similar insulated container

Any container can work, but since you are trying for an equilibrium between ice and water, I think it works best with an insulated container. (I discovered Styrofoam cups can easily split and leak water everywhere when shoving thermometers in the ice...)

Add ice chips (approx. the size of jelly beans) to the thermos such that the ice mounds up over the top. The smaller the ice chips, the better.

Performing the IMP (cont'd)

Keep a pitcher of pre-chilled tap water in the employee refrigerator (nice, not required) and pour in the thermos to 2/3's full. There must be plenty of ice above the water level and resting on the bottom. You do not want the ice to "float". Add additional ice if needed.

Insert the temp probe into the middle of the ice.

IMPORTANT: DO NOT ALLOW THE THERMOMETER OR PROBE TO TOUCH THE BOTTOM OR SIDES OF THE CONTAINER! Your reading will be high!

Performing the IMP (cont'd)

You may want to use a clothes pin or similar device to hold the probe/thermometer in the middle of the ice. After 10 + minutes, read the temperature of the ice/water mixture. If the device reads within 0.5C of Zero C, you win!

(Having a reference thermometer in the ice bath may help you to “trust” you have done the test well – but it is as easy as it seems!)

So I did the IMP and it said -1C...

If testing glass thermometers and it reads “low”, you must look very carefully along the length of the thermometer at the top reservoir to see if you see traces of the fluid. If so, gently re-warm the thermometer and “re-capture” the errant fluid. Repeat the IMP or replace.

If using an electronic thermometer and it reads *outside of +/- 0.5C, discard and replace!*

Verify the thermometer/probe tip is in the ice and touching nothing but water & ice!

How do I test an air data logger?

I have been able to do IMP's on air data loggers, large FridgeTag-2 units, electronic thermometer with probes in small sealed vials of glycol, etc. Just be brave and use several zip lock bags to protect non-water proof units from the ice and water. You might need to wait an hour or more before reading. Also, performing the IMP in a refrigerator keeps the ice from melting as fast. Be creative!

Why The Push For Allowing Ice Melting Point Test (IMP) Validation Annually?

- 1) Teach end users that vaccine storage is different from food storage – you need to “own” the process of verification!

The more they understand about temperature management, the more seriously they will take this job!

Allowing IMP to validate certified thermometers -

2) Discourages a “Race To The Bottom” where users would purchase the cheapest certified thermometer available and replace annually.

- In my office with 3 sites and 10 providers, we have 11 refrigerators and freezers to keep track of! To certify annually, I would have to have two complete sets of thermometers and send off each set every 6 months at \$100-\$250 each. No one will do that! We would have to spend \$100-\$200 per monitor ANNUALLY!

Allowing IMP to validate certified thermometers -

2) (cont'd) Discouraging the Race To The Bottom –

Instead, we would want to invest in vaccine-specific thermometer systems that can be phone enabled, internet enabled, respond to phone queries, be centralized where a single screen can in real time monitor all units, and would be able to “call for help” *before* an event caused loss of vaccine – not after!

Allowing IMP to validate certified thermometers -

3) Per NIST would improve accuracy since the probes would be tested “As is – Where is”.

NIST recommends all sites perform an IMP on all new thermometers in place prior to being put in service. NIST’s new guidelines will require manufacturers to certify product passes and IMP prior certification as a vaccine thermometer!

Allowing IMP to validate certified thermometers -

4) Reduce the “Hassle Factor” of Temperature Management

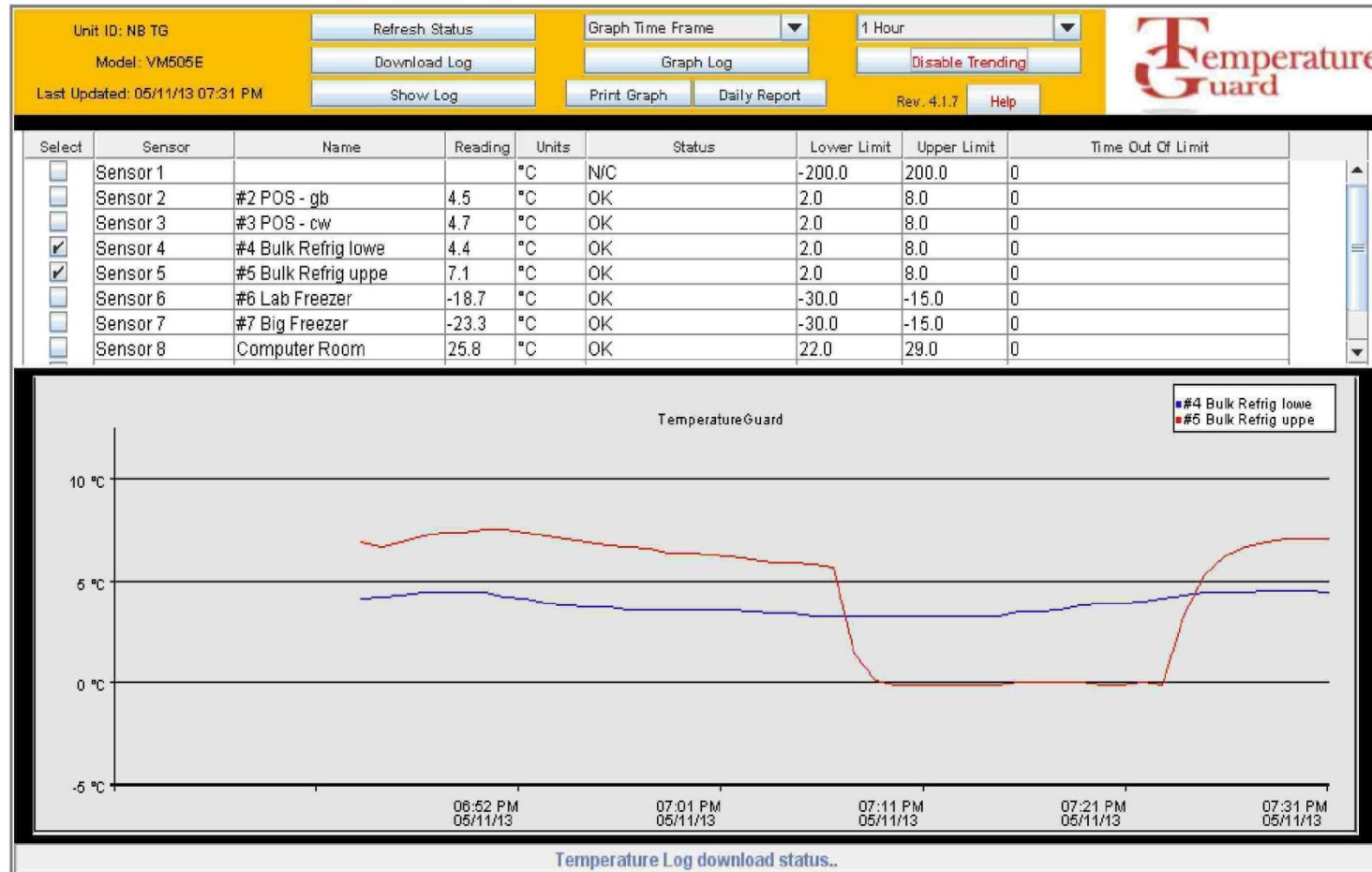
We would not need to constantly learn new data logging thermometers with their ever changing software. We would be able to learn a single system well and know how it works! And no one likes to ship fragile things!

Allowing IMP to validate certified thermometers -

5) The results of the IMP can be easily documented with the new graphing data loggers

The IMP test will be recorded in the normal data stream and a print screen of the test could be included in the documentation with a notation.

Screen Shot of IMP “proving” test was performed to specs
– in this case the probe recorded 0.0 C to -0.1 C which is
well within the +/- 0.5 C standard.



Allowing IMP to validate certified thermometers -

6) IMP a simple process for the VFC Inspectors
to teach and perform during their visits

Faster than waiting for their thermometer in
glycol to equilibrate

Able to teach users and verify their systems to a
high degree of accuracy

Requires very little equipment

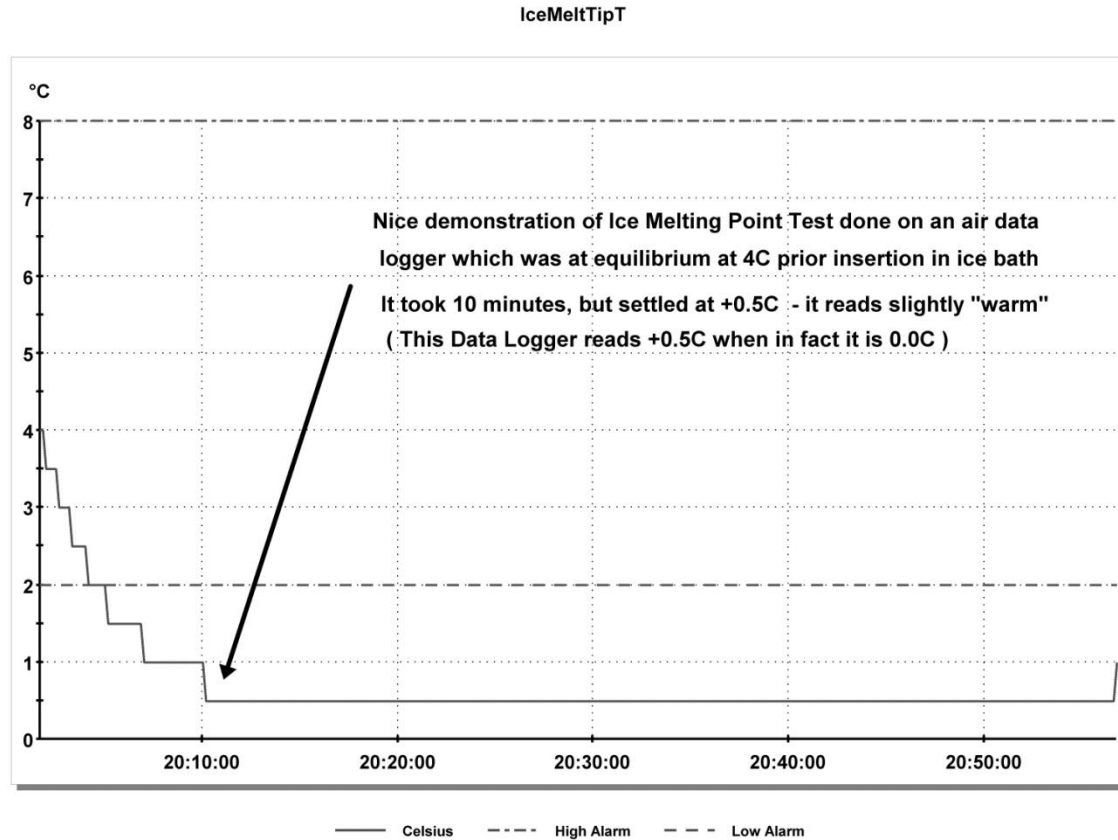
IMP Testing “As Is - Where Is”



IMP Testing “As Is – Where Is”

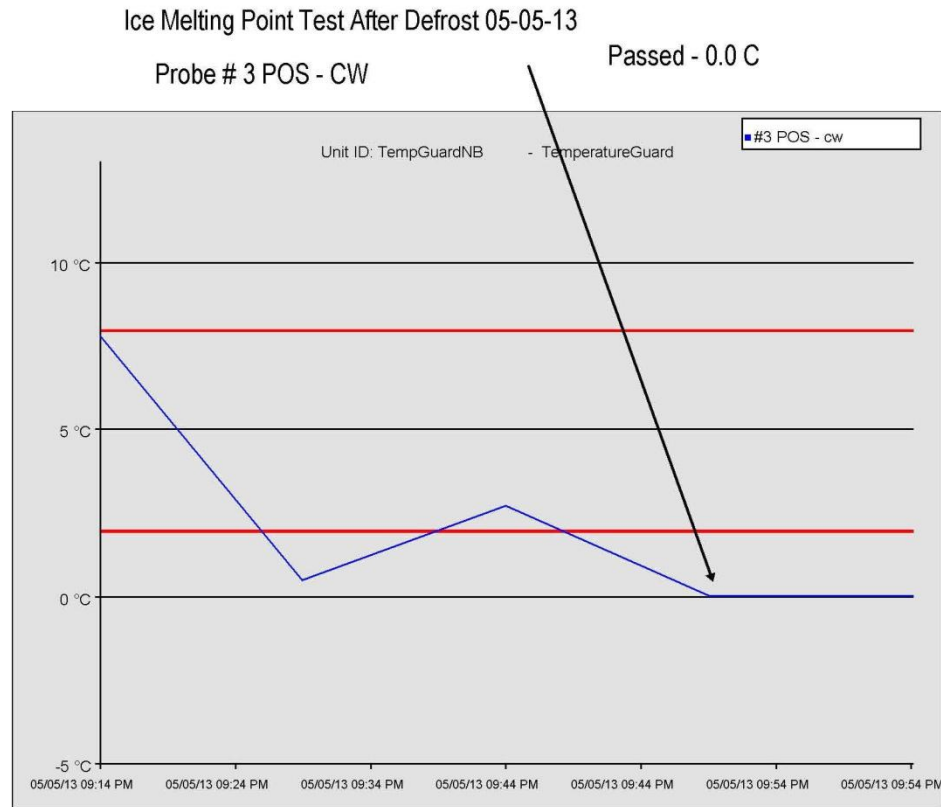


Results Easy To Document



From:- 05 December 2012 20:01:44 To:- 05 December 2012 20:56:44

Results Easy To Document



Summary

Validation via an IMP is not yet a CDC approved procedure – it is my hope that it will be!

It is a very easy test that gives the end-user “ownership” of temperature monitoring. If a thermometer is not making sense – Test It!

IMP testing “As is – Where is” is the least disruptive method of verification– it is what NIST recommends and what we *should* do, even if we can’t yet replace the hassle & expense of professional re-certification!

For More Info on IMP:

NIST Vaccine Management Page

<http://www.nist.gov/pml/div685/grp01/vaccines.cfm>

IMP Video (link on above page as well)

<http://www.youtube.com/watch?v=KYOJayWqB3g>

Verification Methods for Alternative Thermometers

http://www.nist.gov/pml/mercury_validation.cfm

Vaccine Storage and Handling Resources

The following resources help practices store their vaccine safely and maintain the cold chain during transport or disaster. Find them at:

<http://www2.aap.org/immunization/pediatricians/storageandhandling.html>



- Checklist for Maintaining Proper Storage and Handling Practices
- Refrigerators, Freezers, and Vaccine Storage - Data Loggers and Vaccine Monitoring
- Safe Vaccine Transport
- Disaster Planning
- AAP Immunization Training Guide & Practice Procedure Manual
- CDC Vaccine Storage and Handling Toolkit
- CDC Vaccine Storage and Handling Guide
- Video Guidance for Proper Storage and Handling of Vaccines
- Vaccine Storage Temperature Recommendations
- Guidelines for Storage and Temperature Monitoring of Refrigerated Vaccines
- Recording Refrigerator Temperatures
- Recording Freezer Temperatures
- Setting Up Your Refrigerator for Vaccine Storage
- Setting Up Your Freezer for Vaccine Storage
- Storing Vaccines in Your Refrigerator
- Storing Vaccines in Your Freezer
- Temperature Logs for Vaccines - Celsius
- Don't Be Guilty of These Errors in Storage & Handling
- Checklist for Safe Vaccine Storage and Handling
- Ice Point Test for Thermometers
- Refrigerator/Freezer Setup Resources